

## AMENDMENTS TO THE CLAIMS

What is claimed is :

1. (CURRENTLY AMENDED) An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

means for filling the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter from about 10 microns to about 600 microns corresponding to the diameter of previously-embedded solid particles in the shell prior to dissolution by a solvent and located at and near the surface to a depth of about 1800 microns to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.
2. (original) An implantable mammary device according to claim 1, wherein most of the external surface is rough-textured.
3. (CURRENTLY AMENDED) An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly-formed interconnected cells varying in diameter from about 10 microns to about 600 microns corresponding to the diameter of previously-embedded solid particles in the shell prior to dissolution by a solvent and located at and near the surface to a depth of about 1800 microns to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

4. (original) An improved silicone elastomer shell according to claim 3, wherein most of the external surface is rough-textured.

5. (CURRENTLY AMENDED) An implantable mammary device comprising:

a substantially homogeneous silicone elastomer shell of unitary construction defining an interior therein; and

means for filling the interior,

wherein the shell includes a base layer of substantially homogeneous silicone elastomer and an outer layer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface and comprising a substantially homogeneous silicone elastomer, and having defined internally therein a first group of cells varying in diameter from about 10 microns to about 600 microns corresponding to the diameter of a first

group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein and a second group of cells varying in diameter from about 10 microns to about 600 microns corresponding to the diameter of a second group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein relative to the first group of cells, the first group of cells being in direct communication with the external surface and having a range of depths down to about 600 microns below the external surface, and the second group of cells having a range of depths down to about 1800 microns below the external surface, wherein the first and second groups of cells are disposed for creating an open-cell structure, wherein the first group of cells open directly to the external surface, and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

6. (CURRENTLY AMENDED) An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising a shell formed of at least a base layer of silicone elastomer, and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface with at least a portion of said external surface having defined unitarily therein an open-cell structure including a first group of cells varying in diameter from about 10 microns to about 600 microns corresponding to the diameter of a first group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein and a second group of cells varying in diameter from about 10 microns to about

600 microns corresponding to the diameter of a second group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein relative to the first group of cells, the first group of cells being in direct communication with the external surface and having a range of depths down to about 600 microns below the external surface, and the second group of cells having a range of depths down to about 1800 microns below the external surface, the first and second groups of cells creating a network of cells to achieve the open-cell structure, wherein the first group of cells open directly to the external surface and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting tissue ingrowth and for preventing capsular contracture.

7. (original) An improved silicone elastomer shell according to claim 6, wherein most of the external surface has the open-cell structure.

8. (CURRENTLY AMENDED) An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

a filling for the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter according to the diameter of previously-embedded solid particles in the shell prior

to dissolution by a solvent and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

9. (CURRENTLY AMENDED) An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

means for filling the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter according to the diameter of previously-embedded solid particles in the shell prior to dissolution by a solvent and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

10. (original) An implantable mammary device according to claim 9, wherein most of the external surface is rough-textured.

11. (original) An implantable mammary device according to claim 9, wherein the interconnected cells vary in diameter from about 10 microns to about 600 microns.

12. (original) An implantable mammary device according to claim 9, wherein the interconnected cells are located at and near the surface to a depth of about 1800 microns.

13. (CURRENTLY AMENDED) An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly-formed interconnected cells varying in diameter according to the diameter of previously-embedded solid particles in the shell prior to dissolution by a solvent and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

14. (original) An improved silicone elastomer shell according to claim 13, wherein most of the external surface is rough-textured.

15. (original) An improved silicone elastomer shell according to claim 13, wherein the interconnected cells vary in diameter from about 10 microns to about 600 microns.

16. (original) An improved silicone elastomer shell according to claim 13, wherein the interconnected cells are located at and near the surface to a depth of about 1800 microns.

17. (CURRENTLY AMENDED) An implantable mammary device comprising:

a substantially homogeneous silicone elastomer shell of unitary construction defining an interior therein; and

means for filling the interior,

wherein the shell includes a base layer of substantially homogeneous silicone elastomer and an outer layer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface and comprising a substantially homogeneous silicone elastomer, and having defined internally therein a first group of cells varying in diameter according to the diameter of a first group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein and a second group of cells varying in diameter according to the diameter of a second group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein relative to the first group of cells, the first group of cells being in direct communication with the external surface, wherein the first and second groups of cells are disposed for creating an open-cell structure, wherein the first group of cells open directly to the external surface, and the second group of cells communicate with the external surface only through cells which open directly to

the external surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

18. (original) An implantable mammary device according to claim 17, wherein the first and second groups of cells have a diameter ranging from about 10 microns to about 600 microns.

19. (original) An implantable mammary device according to claim 17, wherein the first group of cells have a range of depths down to about 600 microns.

20. (original) An implantable mammary device according to claim 17, wherein the second group of cells have a range of depths down to about 1800 microns.

21. (CURRENTLY AMENDED) An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising a shell formed of at least a base layer of silicone elastomer, and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface with at least a portion of said external surface having defined unitarily therein an open-cell structure including a first group of cells varying in diameter according to the diameter of a first group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein and a second group of cells varying in diameter according to the diameter of a second group of previously-embedded solid particles in the shell prior to dissolution by a solvent formed therein relative to the first group of cells, the first group of cells being in direct communication with the external surface, the first and second groups of cells creating a network of cells to achieve the open-cell structure, wherein the first group of cells open directly to the external surface



and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting tissue ingrowth and for preventing capsular contracture.

22. (original) An improved silicone elastomer shell according to claim 21, wherein most of the external surface has open-cell structure.

23. (original) An improved silicone elastomer shell according to claim 21, wherein the first and second groups of cells have a diameter from about 10 microns to about 600 microns.

24. (original) An improved silicone elastomer shell according to claim 21, wherein the first group of cells have a range of depths down to about 600 microns below the external surface.

25. (original) An improved silicone elastomer shell according to claim 21, wherein the second group of cells have a range of depths down to about 1800 microns below the external surface.

#### **CONDITIONAL PETITION FOR EXTENSION OF TIME**

If any extension of time for this response is required, applicant requests that this be considered a petition therefore. Please charge the required Petition fee to Deposit Account No. **50-3024**.

#### **ADDITIONAL FEE**

Please charge any insufficiency of fees or credit any excess to our Deposit Account No. **50-3024**.